General

Guideline Title

Non-OR procedural safety. Health care protocol.

Bibliographic Source(s)

Farris M, Anderson C, Doty S, Myers C, Johnson K, Prasad S. Non-OR procedural safety. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Sep. 38 p. [4 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Safe site invasive procedure – non-operating room. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Aug. 31 p.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this protocol, refer to Summary of Changes Report – September 2012 .

The recommendations for non-operating room (OR) procedural safety are presented in the form of an algorithm with 12 components, accompanied by detailed annotations. An algorithm is provided in the original guideline document for Non-OR Procedural Safety. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Clinical Highlights

- Procedure sites will be marked with the initials of the provider. The provider will confirm the patient's identity, procedure(s) and site(s) prior to initialing the site. For bilateral procedures, both sides will be marked. (*Annotation #3*)
- A Time-Out will be performed just prior to the start of the procedure, with active verbal confirmation by all the caregivers involved in the care of the patient. The patient should be involved if possible. (*Annotation #7*)
- If site determination is done at the time of the procedure using imaging, verbal confirmation should occur with team/patient, and documentation should reflect use of imaging for site determination. (*Annotation #3*)
- The Time-Out procedure will be repeated for each different, anatomically distinct procedure. (*Annotation #9*)

Special Considerations

Anatomical Variation: When a patient is known to have anatomical variation involving the procedure site, this information should be shared with the care team and additional steps taken to confirm the correct procedure site. This may include additional imaging or a second physician confirming the procedure site.

Single Provider: There are invasive procedures that may involve only one provider. If possible, engage the patient or surrogate in the pre-procedure verification process by asking the patient or surrogate to state the procedure to be performed. This pre-procedure verification is especially important if the provider leaves the patient's room/bedside before performing the invasive procedure.

Non-Operating Room Procedural Safety Algorithm Annotations

1. Pre-Procedure Evaluation, Planning, and Communication
   Verification of the consistency of all patient/procedural information (patient's name, date of birth, medical record number, planned procedure, procedural site and laterality, as applicable) ideally begins at the point of scheduling.

   It is recommended that facilities establish a process to verify the consistency of all patient/procedural information upon receipt of procedure-related documents. Potential sources include:

   - Procedural consent
   - Radiology reports
   - Pathology reports
   - Laboratory results
   - Procedural orders
   - Medical records
   - Physician referrals

   This could take the form of a checklist including the date and signature of the individual who receives and verifies that data are consistent on each document as received.

   All documentation should be provided by paper, fax, or electronic format (not by phone or verbal communication) except in emergent/urgent situations. Ideally, the patient should be provided the same information in hard copy form to bring to the appointment/procedure.

   Discrepancies in the consistency of patient name, date of birth, medical record number, planned procedure, procedural site or laterality should be:

   - Addressed immediately upon discovery
   - Guided by a process (e.g., unit supervisor informed)

   Planning for the procedure must not continue until discrepancy is resolved.

2. Pre-Procedure Verification of Patient, Procedure, and Site
   With the patient awake, the providers/clinicians involved in the care, along with the patient/legal guardian and/or family member, will confirm the patient's identity, procedure and site by comparing the following:

   - Patient's identity, using two patient identifiers
   - Procedure name and site in the informed consent documentation. Multiple procedures are numbered on the consent form with corresponding numbers marked on the patient's skin.
   - Information in the medical record
   - Diagnostic studies
   - Discussion with the patient/legal guardian
   - Interventional radiology: the lesion/site may be identified using intra-procedural imaging, in which case it cannot be marked on the skin. The use of intra-procedural imaging for site verification will then be recorded in the Time-Out documentation.

   The ultimate responsibility for procedure and site verification lies with the provider performing the procedure.

   See Appendix B, "Sample Checklists," in the original guideline document for example of process documentation.

3. Provider Marks Site with Initials if Required
   The provider performing the procedure holds the responsibility for following the correct site-marking process. See the definition of "Site" in the "Definitions" section of the original guideline document for more information.

   General exceptions to site-marking include but are not limited to:

- Emergency procedures
- Midline structures
- Single organ cases (cardiac procedures)

Site-marking has the following characteristics and expectations:

- Site-marking is done following the identification of the patient, review of the consent and other related images as required, and with the patient/family taking part in the process, if able.
- The procedure site will be initialed by the provider using his/her initials with an indelible marker and will be placed such that it is visible when the patient is positioned, prepped and draped.
- Both sites will be marked for bilateral procedures as noted on the consent form.
- For multiple sites/digits on the same anatomical site: each procedure must be numbered independently on the informed consent documentation and each site marked with the appropriate corresponding number.
- For independent procedures on paired anatomical sites (e.g., ears): each procedure must be numbered independently on the informed consent documentation and each site marked with the appropriate corresponding number.
- For procedures involving level (spine or ribs) – The informed consent documentation will indicate the laterality and level, and the site will be marked in a way to indicate anterior or posterior and general level (cervical, thoracic, lumbar, or rib number).
- For imaging-guided procedures, if the side or individual structure is known prior to the procedure start, the site should be marked on the skin.
- Site-marking is also necessary when direct puncture into the area of interest is done based on external landmarks, history or prior studies (rather than intra-procedural imaging) and there is a possibility for left/right or level events.
- For procedures performed by anesthesia – When an anesthesiologist is performing a nerve block or epidural that involves laterality or spine levels, the site should be marked with an "A" with a circle around it to differentiate it from the proceduralist's initials even when the only procedure being performed is by the anesthesiologist.
- For some procedures, the entry site, best approach or treatment site is determined during the first phase of the procedure using radiologic imaging. Verbal confirmation of the final site selection should take place between the provider, the team and the patient (if possible), and documentation following the procedure should reflect the use of imaging to determine the site.

Procedures and situations requiring the use of site-marking diagram:

There should be a written process providing direction on when and how to use the site-marking diagram and how to record this information in the medical record. Guidelines for the use of the diagram include:

- When the site is technically or anatomically impossible to mark (such as a mucosal surface or perineum)
- Teeth – Indicate operative tooth name(s) on informed consent documentation, or mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Premature infants for whom the mark may cause a permanent tattoo. No infants under the corrected gestational age of 38 weeks should be marked.
- Patient refusals to have skin marked – A defined procedure should be in place for documentation of a patient refusal of site-marking, along with the use of the site-marking diagram.
- The use of the diagram should be considered for patients with tattoos at the operative site and the site mark may not be clearly visible.
- The use of the diagram should be considered for patients with anatomical abnormalities that may lead to confusion as to the correct site.

Other situations:

Site-marking is not required when the provider performing the procedure is in continuous physical presence with the patient from arrival for the procedure to conclusion of the procedure. Continuous physical presence means the provider does not leave the room where the procedure will be performed. All the essential patient identifiers, consents, medical records, x-rays and the necessary equipment must be present in the room, and the provider does not leave the room for any reason.

- Interventional procedures where the insertion site is not predetermined (e.g., cardiac catheterization, peripherally inserted central catheters, central lines, arteriogram).
- Procedures that enter through an orifice where the target organ is not associated with laterality (e.g., endoscopies, cystoscopy, laryngoscopy).
- Site-sensitive areas that may be marked above or lateral to the procedure site (e.g., scrotal sites will be marked on the groin area on the appropriate side of the body; breast sites will be marked on the breast or above the breast on the upper chest area).

Sample diagrams are provided in Appendix C, "Body Diagrams," in the original guideline document.

4. Confirmation That All Verification Steps Are Completed; Is Discrepancy Identified?
   A discrepancy is any disagreement over the plan for the patient. A discrepancy in the plan of care could develop or be found at any point in the Safe Site Process. The discrepancy could be found when the patient/legal guardian states what is being done during patient identification/consent/site-marking, medical record, imaging, when the procedure is scheduled, and from team members and/or lack of available equipment.

   If any part of the verification process is not followed and/or a discrepancy is discovered, the procedure is halted and will not continue until the discrepancy is resolved.

   Resolution of discrepancies will include:

   - Reverification of patient identification with at least two patient identifiers (name/medical record number or name/date of birth)
   - Review of the information in the informed consent documentation
   - Review of the medical record
   - Review of diagnostic studies
   - Discussion with the patient/legal guardian (if appropriate)

5. Able to Resolve Discrepancy?
   When a discrepancy is found, the procedure and/or preparation is halted and will not continue until the discrepancy is resolved. This may include a hard stop, meaning the scalpel, needle or cutting/incising device is not handed to the provider until the discrepancy is resolved.

   The complete process for resolution of discrepancies must include the following items:

   - Reverification of patient identification with at least two patient identifiers
   - Review of the information in the informed consent documentation
   - Review of the medical record
   - Review of diagnostic studies
   - Discussion with the patient/legal guardian/family member

   Conversations related to solution of discrepancies will be held in a quiet location, away from activity and distractions. After the discrepancy has been resolved, the procedure and site verification process will be repeated.

   If the steps of the verification process cannot be completed and/or a discrepancy cannot be resolved, the procedure is canceled and rescheduled.

6. Has Time, Team or Location Changed after Verification?
   There is any number of reasons for the care team to change. If any staff changes or additions (such as hand-off, tech-to-tech, observers, lab personnel, etc.) take place, the team member(s) involved in procedure and procedural support should confirm the patient's information including the verification of the patient, procedure and the site. All hand-offs in care before, during or after the procedure should follow a standard process/format that has been agreed upon by the facility. See the "Definitions," section in the original guideline document for the definition of "Structured Hand-Off."

7. Active Time-Out Process with All Team Members; Is Discrepancy Identified?
   The Time-Out is to be performed immediately prior to the start of the procedure and is the final safety stop before the procedure is begun. Every Time-Out must include the following standard elements:

   - Patient identity, using a minimum of two identifiers
   - Procedure(s) to be performed (including internal and/or external laterality, multiples and/or level)
   - Patient positioning if not already verified
   - Procedure side, site and/or level including visualization of the provider's initials if applicable
   - As appropriate, imaging, equipment, implants or special requirements (e.g., pre-procedure antibiotic administration)

   The Time-Out is to be initiated by the provider and includes active verbal acknowledgment by all members of the team. During the Time-Out, each person in the procedure room must stop what he or she is doing and actively participate in the process. No individual is exempt from the process. Active participation requires each individual to state clearly and loudly that they agree with the elements of the Time-Out. The scalpel, needle or other cutting/incising device is not to be handed to the provider until the Time-Out has been completed.

   Environmental distractions are to be eliminated as much as possible during the Time-Out. For example, music is turned off, pagers are set on vibrate, talking other than participation in Time-Out ceases, and no staff are permitted to enter or exit the room. If during the Time-Out an interruption or distraction occurs (pager goes off or an individual enters the room), the Time-Out must be restarted. While it is desirable to

actively include the patient in the Time Out, it is not always possible, particularly if the patient is under the influence of sedating medications or is otherwise unable to participate.

It is recommended that a visual memory aid be used to trigger the initiation of the Time-Out. For example, a "Time-Out" sign or towel can be used to cover the scalpel, needle or cutting/incising device as a reminder to conduct the Time-Out.

The provider may delegate the Time-Out elements to the nurse or other member of the team, but the initiation of the Time-Out should be the responsibility of the provider. The nurse or other team member may refer to the patient consent for the Time-Out elements. However, prior to its use, the consent must have been validated against other documents, such as history and physical, radiology or pathology reports, progress notes, etc. See Appendix B, "Sample Checklists," in the original guideline document.

Additional Time-Outs are to be performed when there are two or more different procedures performed on the same patient during the same procedure period, whether or not the procedures involve a new procedure team. The process and elements of the Time-Out as described above must occur prior to the start of the next procedure. Additional patient identification should be conducted when there is a change in team composition.

If the patient needs to be repositioned during the procedure and this repositioning affects the patient's presentation (e.g., the patient is turned prone), an abbreviated Time-Out including the site, side, level and/or visualization of the provider's initials will be conducted. The Time-Out process will be the same as described above (e.g., elimination of distractions, active participation).

The Time-Out process is a final check prior to the actual procedure being performed. It is recommended that the process be documented in the medical record as a marker of safety procedures. The documentation should reflect the person initiating the Time-Out process; the identification by the second provider of the patient, the site and the procedure being performed, and the completeness of the consent process.

8. Able to Resolve Discrepancy?
   See Annotation #5, "Able to Resolve Discrepancy?"

9. Complete Procedure and Create Appropriate Documentation Prior to Patient Leaving Area
   When the provider is starting a new procedure at a different site, the procedure number is referenced on the consent form and verified with the number marked on the patient. A member of the team will read the procedure and number from the consent form. Each member of the team will verbally acknowledge the procedure being performed prior to starting. This process is completed every time the location and/or procedure changes. Examples include:

   - Multiple procedures – different sites
     - Biopsy of atypical lesions: face, scalp and right forearm
   - Different procedures – multiple sites
     - Cryosurgery actinic keratoses: right cheek, nose, left ear, right forearm, right hand. Incision and drainage cyst at upper back, biopsy of atypical lesion right lower back
     - Cryosurgery verruca at right heel. Biopsy atypical lesion at right leg
     - Cryosurgery actinic keratoses at left arm, right arm, nose and left ear. Biopsy lesion at left cheek and dorsal left hand

   At the completion of the procedure, the provider will create an immediate post-procedure note into the medical record. If the procedure note is being dictated, an abbreviated note will suffice. A final note should include a notation that a Time-Out had been completed.

10. Repeat Verification Process; Is Discrepancy Identified?
    If the procedure time changes, if the provider or care team changes, or if the patient is moved, a repeat verification is required. Refer to verification components in Annotation #2, "Pre-Procedure Verification of Patient, Procedure and Site."

11. Able to Resolve Discrepancy?
    See Annotation #5, "Able to Resolve Discrepancy?"

Clinical Algorithm(s)

A detailed and annotated clinical algorithm for non-OR (non-operating room) procedural safety is provided in the original guideline document .

Scope

Disease/Condition(s)

Any disease or condition requiring an invasive, high-risk, diagnostic, or therapeutic procedure performed outside of the operating room

Guideline Category

Evaluation

Management

Prevention

Clinical Specialty

Anesthesiology

Emergency Medicine

Family Practice

Internal Medicine

Nursing

Pediatrics

Preventive Medicine

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To eliminate wrong site, side, patient, or procedure events performed outside of the operating room setting

Target Population

All patients having an invasive, high-risk, diagnostic, or therapeutic procedure performed not in the operating room but in an office, procedural area, emergency department, or at the bedside

Note: Much of the evidence used in this health care protocol is from studies involving adult patients. However, the work group has made the assumption that the benefit derived from these practices also applies to pediatric patients.

Interventions and Practices Considered

1. Pre-procedure evaluation, planning, and communication
2. Pre-procedure verification of patient, procedure, and site
3. Site marking with provider initials if indicated
4. Confirmation that all verification steps are completed
5. Time-Out process with all team members actively involved
6. Intra-procedure pause when indicated
7. Creating appropriate documentation prior to patient leaving area

Major Outcomes Considered

Not stated

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) Protocols. The literature search was divided into two stages to identify systematic reviews (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 1, 2010, through May 1, 2012.

The PubMed database was searched for literature. Limited searches included universal protocol for wrong site in radiology, endoscopy or catheter labs, bedside procedures, and clinics. Other search terms included wrong site and outside the OR/operating room, wrong site and non-OR, near-miss events, true events, wrong procedure, wrong site and surgical safety.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

Classes of Research Reports

Class	Description
Primary Reports of New Data Collections	
A	Randomized, controlled trial
B	Cohort-study
C	Nonrandomized trial with concurrent or historical controls • Case-control study • Study of sensitivity and specificity of a diagnostic test • Population-based descriptive study
D	Cross-sectional study • Case series • Case report
Reports that Synthesize or Reflect Upon Collections of Primary Reports	
M	Meta-analysis • Systematic review • Decision analysis • Cost-effectiveness analysis
R	Consensus statement • Consensus report • Narrative review
X	Medical opinion

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Document Development

A work group consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2

members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI.

The work group will meet for 3 to 4 three-hour meetings to develop the protocol. Under the coordination of the ICSI staff facilitator, the work group develops the algorithm and writes the annotations, citing literature where appropriate.

Once the final draft copy of the protocol is developed, the document is sent to the ICSI members for review and comment.

Revision Process of Existing Documents

ICSI scientific documents are revised every 12 to 24 months as indicated by changes in clinical practice and literature. For documents that are revised on a 24-month schedule, ICSI checks with the work group on an annual basis to determine if there have been changes in the literature significant enough to cause the document to be revised earlier or later than scheduled. For yearly reviewed documents, ICSI checks with every work group 6 months before the scheduled revision to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Literature Search

ICSI staff, working with the work group to identify any new pertinent clinical trials, systematic reviews, or regulatory statements and other professional guidelines, conduct a literature search.

Revision

The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

A second review by members is indicated if there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations. If a review by members is not needed, the document goes to the Committee for Evidence-Based Practice for approval according to the criteria outlined above.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the protocol. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the protocol.

All member organizations are expected to respond to critical review as this is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

Document Approval

Each document is approved by the Committee for Evidence-Based Practice (CEBP). The committee will review and approve each protocol, based on the following criteria:

- The aim(s) of the document is clearly and specifically described.
- The need for and importance of the document is clearly stated.
- The work group included individuals from all relevant professional groups and had the needed expertise.
- Patient views and preferences were sought and included.
- The work group has responded to all feedback and criticisms reasonably.
- Potential conflicts of interest were disclosed and do not detract from the quality of the document.
- Systematic methods were used to search for the evidence to assure completeness and currency.
- Health benefits, side effects, risks and patient preferences have been considered in formulating recommendations.
- The link between the recommendation and supporting evidence is clear.
- Where the evidence has not been well established, recommendations based on community practice or expert opinion are clearly identified.
- Recommendations are specific and unambiguous.
- Different options for clinical management are clearly presented.
- Clinical highlights and recommendations are easily identifiable.
- Implementation recommendations identify key strategies for health care systems to support implementation of the document.
- The document is supported with practical and useful tools to ease clinician implementation.
- Where local resource availability may vary, alternative recommendations are clear.
- Suggested measures are clear and useful for quality/process improvement efforts.

Once the document has been approved, it is posted on the ICSI Web site and released to members for use.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate safe site invasive procedures when performed outside of the operating room
- Elimination of wrong site, side, patient, or procedure events performed outside the operating room

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- The information contained in this Institute for Clinical Systems Improvement (ICSI) Health Care Protocol is intended primarily for health professionals and other expert audiences.
- This ICSI Health Care Protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care

Protocol and applying it in their individual case.
- This ICSI Health Care Protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

- For ongoing success of this protocol, leadership support, a local/unit-based champion, and a multidisciplinary steering team are absolutely essential.
- Establish pre-procedure and intra-procedural communication standards in the form of structured hand-offs, huddles, pre-procedure briefings, etc.
- Create a process that addresses how to document completion of each step and ensure that all elements of the protocol are completed. A checklist may be used (see Appendix B in the original guideline document for a sample Pre-Procedure hard copy checklist, and for a sample checklist within an Electronic Medical Record [EMR]).
- A visual reminder to complete the "Time-Out" is recommended.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Quality Measures

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Non-OR procedural safety: percentage of wrong invasive or high-risk procedure events outside of the operating room per month.

Non-OR procedural safety: percentage of invasive or high-risk procedures outside of the operating room that met observational compliance.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Farris M, Anderson C, Doty S, Myers C, Johnson K, Prasad S. Non-OR procedural safety. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Sep. 38 p. [4 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2008 Sep (revised 2012 Sep)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers; Allina Medical Clinic; Aspen Medical Group; Baldwin Area Medical Center; Brown Clinic; Center for Diagnostic Imaging/Medical Scanning Consultants; CentraCare; Central Lakes Medical Clinic; Chippewa County – Montevideo Hospital & Clinic; Cuyuna Regional Medical Center; Essentia Health; Fairview Health Services; Family HealthServices Minnesota; Family Practice Medical Center; Fergus Falls Medical Clinic; Gillette Children's Specialty Healthcare; Grand Itasca Clinic and Hospital; Hamm Clinic; HealthEast Care System; HealthPartners Central Minnesota Clinics; HealthPartners Medical Group & Regions Hospital; Hennepin County Medical Center; Hennepin Faculty Associates; Howard Young Medical Center; Hudson Physicians; Hutchinson Area Health Care; Hutchinson Medical Center; Integrity Health Network; Lake Region Healthcare Corporation; Lakeview Clinic; Mankato Clinic; MAPS Medical Pain Clinics; Marshfield Clinic; Mayo Clinic; Mercy Hospital and Health Care Center; Midwest Spine Institute; Minnesota Association of Community Health Centers; Minnesota Gastroenterology; Multicare Associates; New Richmond Clinic; North

Central Heart Institute; North Clinic; North Memorial Health Care; Northwest Family Physicians; Obstetrics and Gynecology Specialists; Olmsted Medical Center; Park Nicollet Health Services; Planned Parenthood Minnesota, North Dakota, South Dakota; Quello Clinic; Raiter Clinic; Rice Memorial Hospital; Ridgeview Medical Center; River Falls Medical Clinic; Riverwood Healthcare Center; South Lake Pediatrics; Southside Community Health Services; Stillwater Medical Group; University of Minnesota Physicians; Winona Health

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Source(s) of Funding

- The Institute for Clinical Systems Improvement (ICSI) provided the funding for this protocol. The annual dues of the member medical groups and sponsoring health plans fund ICSI's work. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.
- ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups, and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Guideline Committee

Committee on Evidence-Based Practice

Composition of Group That Authored the Guideline

Work Group Members: Marietta Farris, BSN (*Work Group Leader*) (Fairview Health Services) (Nursing); Christina E. Anderson, MD (Chippewa County – Montevideo Hospital & Clinic) (Family Medicine); Stephanie Doty, MSN, MBA, RN (HealthPartners Medical Group and Regions Hospital) (Patient Safety & Quality); Shailendra Prasad, MBBS, MPH (University of Minnesota) (Family Medicine); Kari Johnson, RN (Institute for Clinical Systems Improvement [ICSI]) (Clinical Systems Improvement Facilitator); Cassie Myers (ICSI) (Systems Improvement Coordinator)

Financial Disclosures/Conflicts of Interest

The Institute for Clinical Systems Improvement (ICSI) has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at the ICSI Web site.

Disclosure of Potential Conflicts of Interest

Christina Anderson, MD (Work Group Member)
Family Physician, Family Medicine
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: ICSI Rapid Response Team Protocol
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Stephanie Doty, MSN, MBA, RN (Work Group Member)
Director of Patient Safety, Patient Safety and Quality Department, Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: ICSI Rapid Response Team Protocol; ICSI Prevention of Retained Foreign Objects During Labor and Delivery Protocol; ICSI Perioperative Protocol; ICSI Committee on Evidence-Based Practice
Research Grants: None
Financial/Non-Financial Conflicts of Interest: holds stock in 3M

Marietta Farris, BSN, MAN (Work Group Leader)
Nurse Manager, Medical/Surgical, Fairview Health Services, University of Minnesota Medical Center
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Shailendra Prasad, MBBS, MPH (Work Group Member)
Assistant Professor, Family Medicine, University of Minnesota
National, Regional, Local Committee Affiliations: None
Guideline-Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Safe site invasive procedure – non-operating room. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Aug. 31 p.

Guideline Availability

Electronic copies: None available.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425.

Availability of Companion Documents

Resources including sample checklists (Pre-Procedure Verification Checklist; Electronic Checklist of Pre-Procedure Assessment, Pre-Procedure Verification and Time-Out) and body diagrams are available in the appendices to the original guideline document.

Patient Resources

None available

NGC Status

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